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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,000	11/28/2000	Anthony J. Polverino	MBHB00-450-A	6633

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EXAMINER

RAWLINGS, STEPHEN L

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/724,000

Applicant(s)

POLVERINO ET AL.

Examiner

Stephen L. Rawlings, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 9,13,14,16,46,47,57 and 59-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9,13,16, 57, 59, and 60 is/are allowed.
- 6) ☒ Claim(s) 14,46,47 and 61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 November 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. The amendment filed April 18, 2005 has been entered. Claims 9, 14, 57, and 61 have been amended.
2. Claims 9, 13, 14, 16, 46, 47, 57, and 59-61 are pending in the application.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Grounds of Rejection Withdrawn***

4. Unless specifically reiterated below, Applicant's amendment filed April 18, 2005 has obviated the grounds of rejection set forth in the preceding Office action mailed November 18, 2004.

#### ***Grounds of Rejection Maintained***

##### ***Claim Rejections - 35 USC § 112***

5. The rejection of claims 14, 46, 47, and 61 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

At pages 5-7 of the amendment filed April 18, 2005, Applicant has traversed this ground of rejection.

Applicant's arguments have been carefully considered but not found persuasive for the following reasons:

The considerations that are made in determining whether a claimed invention is supported by an adequate written description are outlined by the published Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, "Written Description"

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Requirement (Federal Register; Vol. 66, No. 4, January 5, 2001). A copy of this publication can be viewed or acquired on the Internet at the following address: <http://www.gpoaccess.gov/>.

Applicant has argued, “the specification *inherently* discloses polypeptide fragments of at least about 25 amino acid residues, but not more than 80 amino acid residues, of human Secs-1 polypeptide” (page 6, paragraph 3). In response, it is not considered pertinent whether the specification *inherently* discloses polypeptide fragments of at least about 25 amino acid residues, but not more than 80 amino acid residues, of human Secs-1 polypeptide. The question is whether the specification would reasonably convey to the skilled artisan that Applicant had possession of the claimed invention at the time the application was filed. There are multiple means by which the specification might show that Applicant had possession of the claimed invention at the time the application was filed. For example, the specification might show that Applicant had possession of the claimed invention at the time the application was filed by describing a representative number of members of the claimed genus of polypeptides, such that the skilled artisan could immediately envision, recognize, or distinguish at least a substantial number of those members. In this instance, however, claims 14, 46, and 47 are directed to members of a genus of proteins and fusion proteins that merely comprise a fragment of the polypeptide of SEQ ID NO: 5. Accordingly, claims 14, 46, and 47 are directed to members of a genus of structurally and functionally different proteins and fusion proteins. Although the specification describes the polypeptide of SEQ ID NO: 5, this polypeptide is not reasonably deemed representative of the claimed genus, as a whole, because the specification fails to describe how this polypeptide is representative of the genus as a whole by, for example, disclosing that each member of the claimed genus of polypeptides may be recognized or discerned by the presence in its structure of a particularly identifying (i.e., substantial) feature that correlates with the common ability of each member to function in a particularly identifying manner.

Again, Applicant is reminded that Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, “Written Description” Requirement (66 FR 1099-1111, January 5, 2001) states, “[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was ‘ready for patenting’ such as by disclosure of drawings or structural chemical formulas that show that the invention was

complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention” (*Id.* at 1104). “Guidelines” further states, “[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot* be achieved by disclosing only one species within the genus” (*Id.* at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus. Because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was “ready for patenting” by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant had possession of the claimed invention at the time the application was filed.

With regard to claim 61, it, too, is broadly but reasonably interpreted to be directed to a genus of structurally and functionally disparate proteins, which are encoded by a nucleic acid molecule comprising a nucleotide sequence of a region of the nucleotide sequence of either SEQ ID NO: 4 or a DNA insert encoding a Secs-1 polypeptide in ATCC deposit no. PTA-1755. As amended, the claimed members of the genus of polypeptides are encoded by a nucleic acid molecule that encodes a polypeptide fragment of at least 25 amino acid residues, but not more than 80 amino acid residues; however, inasmuch as the claim encompasses polypeptides encoded by a nucleic acid molecule encoding any such fragment of any polypeptide, and not necessarily such a fragment of the polypeptide of SEQ ID NO: 5, the claims are drawn to a genus comprising widely variant members. Notably, also, the claimed polypeptides are encoded by a nucleic acid encoding such a fragment of a polypeptide, but are not necessarily limited to those polypeptides encoded by a nucleic acid molecule that encodes only the fragment, as opposed to a polypeptide comprising such a fragment. Accordingly, even if the claim recited that the nucleic acid molecule encodes such a polypeptide fragment of SEQ ID NO: 5, as opposed to such a

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polypeptide fragment of any protein, the claims would still encompass polypeptides encoded by a nucleic acid encoding such a polypeptide fragment of SEQ ID NO: 5 but not necessarily to polypeptides that *consist of* polypeptide fragments of SEQ ID NO: 5.

Applicant has argued that one of ordinary skill in the art would be able to readily envision every member of the claimed genus of polypeptide fragments. To the contrary, the skilled artisan could only envision members of the claimed genus of polypeptide fragments that consist of fragments of the polypeptide of SEQ ID NO: 5; the specification would not, however, permit the skilled artisan to immediately envision the other members of the claimed genus of polypeptides, which comprise fragments of the polypeptide of SEQ ID NO: 5 (claims 14, 46, and 47) or fragments of some unspecified protein (claim 61).

Applicant has argued that one of ordinary skill in the art could readily determine the structure of polypeptide fragments of SEQ ID NO: 5. In reply, although one of ordinary skill in the art could readily determine the structure of polypeptide fragments of SEQ ID NO: 5, the claims are not limited to polypeptides that are fragments of the polypeptide of SEQ ID NO: 5, or to fusion proteins comprising fragments of SEQ ID NO: 5 and heterologous amino acid sequences.

### ***Conclusion***

6. Claims 9, 13, 16, 57, 59, and 60 are allowed. Claims 14, 46, 47, and 61 have been rejected.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

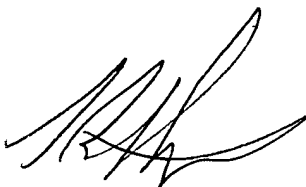
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.  
Examiner  
Art Unit 1642

slr  
June 15, 2005



LARRY R. HELMS, PH.D  
PRIMARY EXAMINER